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Brian Barrett
ELI LILLY AND COMPANY
PATENT DIVISION/BPB
LILLY CORPORATE CENTER
INDIANAPOLIS IN 46285

In Re: Patent Term Extension
Application for
U.S. Patent No. Re. 37,806
(Original Patent No. 5,681,932)

NOTICE OF FINAL DETERMINATION
AND
REQUIREMENT FOR ELECTION

A determination has been made that U.S. Patent No. Re. 37,806, which claims the human biological product XIGRIS® (drotrecogin alpha), is eligible for patent term extension under 35 U.S.C. § 156. The period of extension has been determined to be 389 days.

A single request for reconsideration of this final determination as to the length of extension of the term of the patent and/or a response to this requirement for an election may be made if filed within one month of the date of this notice. Extensions of time under 37 CFR § 1.136(a) are not applicable to this time period. In the absence of such request for reconsideration or election, the Director will issue a certificate of extension in U.S. Patent No. 4,775,624 for a period of 1,397 days. See 37 CFR 1.785(b).

Under 35 U.S.C. § 156(c), the period of extension is calculated using the Food and Drug Administration's determination of the length of the regulatory review period published in the Federal Register of November 25, 2003 (68 Fed. Reg. 66112).

$$\begin{aligned}\text{Period of Extension} &= \frac{1}{2} (\text{Testing Phase}) + \text{Approval Phase} \\ &= \frac{1}{2} (2193 - 1,007) + 300 \\ &= 1,397 \text{ days (3.8 years)}\end{aligned}$$

The regulatory review period began January 26, 1995, before the original patent issued (October 28, 1997). Because a patent may only be extended by the time "equal to the regulatory review period for the approved product which period occurs after the date the patent is issued" the period from January 26, 1995 to and including October 28, 1997 (1,007 days) has been subtracted from the "testing phase" in the above calculation. No determination of a lack of due diligence under 35 U.S.C. § 156(c)(1) was made.

The 14 year exception of 35 U.S.C. § 156(c)(3) operates to limit the term of the extension in the present situation, however, because it provides that the period remaining in the term of the patent measured from the date of approval of the approved product plus any patent term extension cannot exceed fourteen years. The period of extension calculated above, 1,397 days, would extend the patent from October 28, 2014 (35 U.S.C. § 154) to April 8, 2017, which is beyond the 14-year limit (the approval date is November 21, 2001, thus the 14 year limit is November 21, 2015). The period of extension is thus limited to November 21, 2015 by operation of 35 U.S.C. § 156(c)(3). Accordingly, the period of extension is the number of days to extend the term of the patent from its original expiration date, October 28, 2014, to and including November 21, 2015, or 389 days.

The limitations of 35 U.S.C. § 156(g)(6) do not operate to further reduce the period of extension determined above.

Applicant has also filed applications for patent term extension for U.S. Patent Nos. 4,775,624 and 5,270,040 based upon the regulatory review of the product XIGRIS®. No more than one patent may be extended based upon the regulatory review period of a product. 35 U.S.C. § 156(c)(4). When applications are filed for extension of the terms of different patents based upon the same regulatory review period for a product, the certificate of extension is issued to the patent having the earliest date of issuance unless applicant elects a different patent. Applicant is hereby REQUIRED TO ELECT a single patent for extension. In the absence of an election by applicant of another patent within ONE MONTH of the date of this notice, and in accordance with 37 CFR 1.785(b), the application for patent term extension in U.S. Patent No. 4,775,624 will be granted.

Upon issuance of the certificate of extension, the following information will be published in the Official Gazette:

U.S. Patent No.: Re, 37,806
Reissued: July 23, 2002
Original Expiration Date¹: October 28, 2014
Applicant: Brian W. Grinnel
Owner of Record: Eli Lilly and Company
Title: Method of Using Eukaryotic Expression Vectors Comprising the BK Virus Enhancer
Product Trade Name: XIGRIS® (drotrecogin alpha)
Term Extended: 389 days
Expiration Date of Extension: November 21, 2015

Any correspondence with respect to this matter should be addressed as follows:

By mail: Mail Stop Patent Ext.
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450.

By FAX: (571) 273-7744

Telephone inquiries related to this determination should be directed to the undersigned at (571) 272-7744.



Karin Ferriter
Senior Legal Advisor
Office of Patent Legal Administration
Office of the Deputy Assistant Commissioner
for Patent Policy and Projects

cc: Office of Regulatory Policy
HFD - 13
5600 Fishers Lane
Rockville, MD 20857

Attention: Claudia Grillo

RE: XIGRIS® (drotrecogin alpha)
FDA Docket No.: 02E-0255

¹Subject to the provisions of 35 U.S.C. § 41(b).